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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,585	09/26/2003	Gilles Gosselin	18085.105102	8655

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EXAMINER
CRANE, LAWRENCE E

ART UNIT	PAPER NUMBER
1623	

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DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/672,585	GOSSELIN ET AL.	
	Examiner	Art Unit	
	L. E. Crane	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *July 27, 2005 (amdt)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,12 and 14-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-9,12 and 14-17* is/are rejected.

7)☒ Claim(s) *5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims **10, 11 and 13** have been cancelled, claims **1-9, 12 and 14-16** have been amended, and new claim **17** has been added as per the amendment received July 27, 2005. No additional Information Disclosure Statements (IDSs) have been received as of the date of this Office action.

Claims **1-9, 12 and 14-17** remain in the case.

Note to applicant: when a rejection refers to a claim **X** at line y, the line number "y" is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

In the instant disclosure the "Cross-References to Related Applications" is not up to date. Applicant is respectfully requested to update the status information in the first paragraph of the disclosure.

The disclosure is objected to because of the following informalities:

At the end of the specification there is a paragraph which identifies the "Legend of Figure 1." Earlier in the disclosure there is reference made briefly to the contents of Figures 1 and 2, but at no point is there is section with the header "Brief Description of the Drawings. Examiner suggests that the instant disclosure needs to be amended to conform to US requirements in re description of the drawings (latitude will be allowed to more completely describe the contents of the drawings) and that the "legend" needs to be moved from the disclosure to the Figure(s) as appropriate.

Appropriate correction is required.

Claims **12 and 15** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims have not met the written description standard because the instant specification at pages 19-20 only discloses the treatment of HIV infected cell lines, and does not teach treatment of any other viral infections. Also, the compounds tested are limited to ß-L-DDC and ß-L-5-fluoroDDC, and therefore there is no description of the testing of the vast majority of compounds encompassed by the instant methods claims against any viral disease condition.

Applicant's arguments with respect to claims **12 and 15** have been considered but are deemed to be moot in view of the new grounds of rejection. This rejection was necessitated by applicant's amendment of the noted claims.

Claims **12 and 15** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention; the scope is excessive in view of the disclosed enabling exemplifications.

The definitions of both compounds and viral conditions to be treated therewith in claims **12 and 15** are directed to a vast number of species which have not been described in the instant disclosure in a manner permitting the ordinary practitioner to have the guidance necessary to use a very large proportion of the compounds encompassed in the treatment of any viral disease condition. Examiner finds only two compounds (ß-L-DDC and ß-L-5-fluoroDDC) provided in the "Examples" section and, aside from inhibition of HIV, neither of these compounds has been shown to have the implied broad-spectrum antiviral effect on virally infected cells. In addition, the term "virally infected cell" extends to all viral infections regardless of whether a disease condition is a consequence of the infection or not, another indication of excessive claim scope.

Claims **12 and 15** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The fundamental issue here is whether practicing the full scope of the instant invention is possible without undue experimentation. As provided for in *In re Wands* (858 F.2d 731, 737; 8

USPQ 2d 1400, 1404 (Fed Cir. 1988) the minimum factors to be considered in determination of whether a conclusion of "undue experimentation" is appropriate are as follows:

A. The breadth of the claims: the instant claims extend to the treatment of all viral infections including HIV by administration of a mono-deoxynucleoside compound of claims **8 and 9** as the active ingredients in the treatment of said viral infections.

B. The nature of the invention: the invention is directed to the treatment of viral infections by administration of an L-mono-deoxynucleoside to a host cell infected with a disease-causing virus.

C. The state of the prior art: L-dideoxynucleosides are well known in the prior art and have been prospectively disclosed by the prior art cited elsewhere herein as having antiviral activity, particularly including having been shown to be effective in the inhibition of HIV. However, this prior art statement cannot be made about mono-deoxynucleosides.

D. The level of one of ordinary skill: the level of skill is moderate in the area of 2',3'-dideoxynucleoside administration to treat HIV and other retroviral infections but does not extend beyond this to viral disease treatments in general. However, the state of the art noted above does not extend to mono-deoxynucleosides which, because they are not nucleic acid chain terminators, will certainly not behave like the tested compounds.

E. The level of predictability in the art: predictabililty is low because not all compounds of the generic mono- and di-deoxynucleoside/nucleotide compounds have been shown to have antiviral or anti-HIV activity, thereby requiring a showing of activity.

F. The amount of direction provided by the inventor: the medicinal testing portion of the instant disclosure (pp. 19-20) is limited to the testing of ß-L-DDC and ß-L-5-fluoroDDC against cells infected with HIV in culture. No testing of other viral infections was disclosed. Also there was not test data disclosed for the antiviral activity of L-monodeoxynucleosides.

G. The existence of working examples: the working examples are noted in the previous paragraph.

H. The quantity of experimentation needed to make or use the invention based on the content of the disclosure: the examples provided in the disclosure only enable the treatment of two strains of HIV with dideoxynucleosides, not monodeoxynucleosides, and therefore undue experimentation will be essential to establish how any other viral disease conditions may be effectively treated with the array of
L-monodeoxynucleoside compounds within the scope of claims **8 and 9**.

Claims **1, 3, 4, 7, 8, 9, 12 and 14-16** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim **1** at lines 10-14, the process step has not been completely defined; i.e. is "B" an unprotected base, or a protected base, and if the latter, what particular protecting group or groups is/are present. The subsequent definition at lines 17 is incomplete also because the optional protection has not been defined. In addition it is very well known in the nucleoside synthesis art that unprotected bases are not preferred and that protection is essential to achieve reasonable yields. Therefore, the instant process is incomplete for failure to define the different process conditions required depending on whether protection is present or absent.

In claim **1** at lines 15-16, examiner suggests that the term "such as an acyl, benzoyl, benzyl or silyl group" has two flaws: the term "such as" in the instant context suggests confusion concerning the intended scope of the claimed subject matter (see previous office action by Examiner Owens for cites on this topic) and to be properly grammatical the subsequent list should be rewritten as follows -- an acyl, a benzoyl, a benzyl or a silyl group -- . See also claim **4** wherein a similar problem occurs beginning with the term "in particular."

In claim **1** at line 17, the term "optionally substituted" is incomplete because no "optional" substituents have been defined.

In claim **1** at step 3, the term "removed" is functional and fails to define the particular chemical process step or process steps which may be applied to effect this transformation thereby rendering the claim indefinite for lack of completeness.

In claim **3** at line 3, the term "prepared by acetolysis" renders the instant claim lacking in proper antecedent basis because the noted term represents a chemical step not provided for in

the definitions of claims **1 or 2**. Examiner suggests -- further comprising -- language as a solution to this problem.

In claim **7** at lines 1-5, the process being claimed has two flaws:
i) said claim lacks antecedent basis in claim **1** because claim **1** does not provide for conversion of the base moiety U to the base moiety C and
ii) the steps of particular chemical process being claimed have not been defined thereby rendering the claim incomplete.

In claim **8** at line 1, the term "compounds" is incorrect. Did applicant intend the term to read -- compound --.

Claim **9** is improperly dependent because it is styled as "the compound" when it depends from a "method" claim **7**. Examiner suggests that amendment of the preamble would solve this problem. Alternatively, if applicant intended dependence from claim **8**, then in claim **9** the term "characterized in that" is presumed to be open language ala -- comprising --, and therefore said term renders the instant claim both improperly dependent from claim **8** which is defined narrowly ("corresponding to" language is deemed to be a "consisting of" equivalent) and indefinite because the noted term, like comprising, implies the presence of subject matter not defined in either of claims **8 or 9**. Examiner suggests claim **9** should depend from claim **8** and the noted term of art in claim **9** should be replaced with -- consisting of --. If not, then claims **12 and 14-16** are also improperly dependent method of treatment claims because they depend from method of making claim **7**.

Claim **9** is improperly dependent because it is styled as "the compound" when it depends from a "method" claim. Examiner suggests that amendment of the preamble would solve this problem.

Claims **12 and 14-16** are incomplete because no -- host in need thereof -- has been specified.

Claims **15 and 16** lack proper antecedent basis in claims **12 and 14** because the first noted claims are directed to methods of treatment which require administration of dideoxynucleoside compounds while the definitions of claims **8 and 9** only provide for

monodeoxynucleosides which are the only active ingredients presently defined within claims **12 and 14.** .

Note to applicant: with the exception of claim **9** wherein a rejection notes this particular term, in this application the term "characterized in that" has replaced the term of art usually found in process and method claims. In light of the fact that the term "comprising" is judicially recognized to be open language examiner suggests, but does not require, substitution of the latter term within the instant claims to insure complete coverage and the absence of any questions concerning the ability to exclude of infringers should this case issue.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

"A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

Claims **12 and 14-16** are rejected under 35 U.S.C. §102(**b**) as being anticipated by **Farina et al. '884** (PTO-1449 ref. **BP**).

Applicant is directed to page 17 wherein a viral infection has been effectively treated by administration of a compound claimed herein as an active ingredient in the treatment of viral infections including HIV.

Applicant's arguments with respect to claims **12 and 14-16** have been considered but are deemed to be moot in view of the new grounds of rejection.

Claims **1, 2, 5, 12 and 14-17** are rejected under 35 U.S.C. §102(**b**) as being anticipated by **Johansson et al. '248** (PTO-1449 ref. **BS**).

Applicant is referred to pages 7-10 of the **'248** reference wherein the details of preparation and the details of medicinal testing read on and therefore anticipate the instant claimed subject matter.

Applicant's arguments with respect to claims **12 and 14-16** have been considered but are deemed to be moot in view of the new grounds of rejection.

Claim **5** is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims **3, 4 and 6-9** would be allowable if rewritten or amended to overcome the rejections under 35 U.S.C. §112.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(f) or (g) prior art under 35 U.S.C. §103(a).

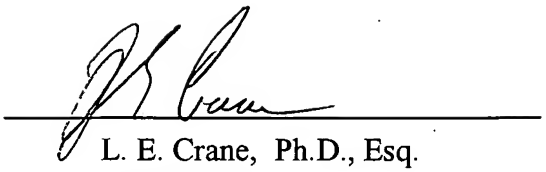
Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

LECrane:lec
01/04/2005



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